K083135

OCT 31 2008

510(k) Summary of Safety and Effectiveness

This summary of safety and effectiveness is provided as part of a Premarket Notification in compliance with the Safe Medical Device Act of 1990 revisions to 21 CFR, Part 807.92, Content and Format of a 510(k) Summary.

Submitter Information

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Date Summary Prepared: June 27, 2008

Device Information

ChillBuster® Model 8002 Portable Electric Blanket, with CDRH formal identity:

Device Group:	System, Thermal Regulating
Medical Specialty:	Cardiovascular
Product Code:	DWJ
Device Class:	2
Regulation No:	870.5900

Predicate Devices

#K071918 ChillBuster® Model 8002 Portable Electric Blanket; ThermoGear Inc;
#K072513 DM-EMG Hypothermic Therapy System; Medvation LLC.

Device Description

This device, as now cleared, permits use with either a sterile or a non-sterile blanket cover, as necessary, upon the determination by a health care practitioner. Most intended use does not involve surgery. Also, even during surgery, only those interventions where the blanket cover would threaten a sterile operating field actually require a sterile blanket cover to achieve intended function.

The present design modification involves no change to intended use, indications for use, technological basis, device design, or substantial equivalence. And both the ChillBuster® Predicate and Modified devices require use of a blanket cover with every therapy session. For ThermoGear's ChillBuster® product, the only Predicate/Modified device difference lies in labeling that addresses when to use a sterile versus non-sterile blanket cover.

While the Predicate 8002 requires use of a sterile blanket cover for every therapy, the Modified 8002 "requires the decision to use a sterile or a non-sterile blanket cover to be made by a medical practitioner, familiar with the patient's condition and circumstance." This improves practicality, while not sacrificing device safety and effectiveness.

Intended Use

There is no difference in intended use of the Modified versus Predicate devices.

The ChillBuster® Model 8002 Portable Electric Blanket has been developed to reduce the effects of hypothermia encountered during the trauma of a surgical procedure or other medical crisis which could result in the onset of a hypothermic condition.

For both the Modified and Predicate devices, use is limited to whole-body warming in adult humans, free of skin conditions or other impairments where distributed heat application is deemed contraindicated by the responsible physician.

Technological Characteristics

The elements of the ChillBuster® system that comprise the current subject, sterile and non-sterile blanket covers, are exactly the same in both the Modified and Predicate devices. The only difference is in labeling related to when to use sterile covers compared to non-sterile ones. The latter is treated in prior discussion.

Non-Clinical Performance Data

Clearance of the subject of this submittal, requirements of when to use a sterile or non-sterile blanket cover, does not require performance data. The two cover types are the same in every way, save the state of sterility. Practitioners can be expected to know the functional properties of sterile versus non-sterile single-use products. The present design change merely replaces an overly restrictive requirement for sterile cover use with one that is practical in the real world.

Conclusion

The ChillBuster® Modified 8002 is substantially equivalent to the ChillBuster® Predicate 8002 at all levels of system design. The subject here is an upgrade of labeling, to render required use of a sterile blanket cover only when the attending practitioner judges such protection is needed. This provides better clarity to assure safer and more effective use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 31 2008

Microtek Medical, Inc.
c/o Mr. Tamas Borsai
TUV Rheinland of North America, Inc.
12 Commerce Road
Newton, CT 06470

Re: K083135
ChillBuster Portable Electric Blanket, Model 8002
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulating System
Regulatory Class: Class II
Product Code: DWJ
Dated: October 2, 2008
Received: October 23, 2008

Dear Mr. Borsai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Device
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K083135

Device Name: *Chill*Buster® Model 8002 Portable Electric Blanket

Indications for Use: The *Chill*Buster® Model 8002 has been developed to reduce the effects of hypothermia encountered during the trauma of a surgical procedure or other medical crisis which could result in the onset of a hypothermic condition. Use is limited to whole-body warming in adult humans, free of skin conditions or other impairments where distributed heat application is deemed contraindicated by the responsible physician.

Prescription Use X AND/OR **Over-The-Counter Use** __
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart D)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K083135